

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated June 3, 2003 are respectfully requested. Submitted with this amendment is a Request for Continued Examination under 37 C.F.R. §1.114 and an Information Disclosure Statement.

Applicants thank the Examiner for an indication that claims 59-62, 67-68, 70-73, 92-93, and 95-99 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claim.

I. Amendments

Claims 1 and 57 are amended to recite that the sensor is an optical sensor operatively connected to function as an emitter and a detector. These claims are further amended to include a switching device. Support for these amendments can be found on page 13, lines 5-8.

Claim 11 is amended to depend from claim 6.

Claim 29 is amended to depend from claim 2.

Claim 31 is amended to depend from claim 3.

Claim 36 is amended for proper antecedent basis.

Claim 77 is amended to depend from claim 57. Claim 77 is further amended for clarity.

New claims 105 and 106 find support in original claims 4 and 77.

By these amendments, no new subject matter has been added.

II. Objection to the Claims

Claims 11 and 77 were objected to as depending from cancelled claims. Claims 11 and 77 are amended to properly recite dependency.

III. Rejections under 35 C.F.R. §103

Claims 1-9, 11, 18-19, 23-25, 29, 31-37, 39, 42-44, 57-58, 69, 74-75, 77, 82-84, and 89 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.* (U.S. Patent No. (5,735,847) in view of Benaron *et al.* (U.S. Patent No. 5,762,609).

Claims 47, 48, and 53 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.* in view Benaron *et al.* and further in view of Hoey *et al.* (U.S. Patent No. 6,409,722).

Claims 40 and 41 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.* in view of Benaron *et al.* and further in view of Edwards *et al.* (U.S. Patent No. 6,092,528).

These rejections are respectfully traversed.

A. The Present Invention

The present invention, as embodied by claim 1, describes a method of treating a tumor comprising providing a tissue biopsy and treatment apparatus for detecting and treating a tumor, where the apparatus comprises an elongated delivery device including a lumen and a sensor array deployable from the elongated delivery device. The sensor array includes a plurality of resilient members each having a tissue piercing distal portion. At least one of the plurality of resilient members is positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state. At least one of the plurality of resilient members includes an optical sensor operatively connected to function as an emitter and a detector and the sensor array has a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site. An optical switching device switches the mode of the optical sensor. At least some of the plurality of resilient members are electrodes which can be coupled to an RF energy source for ablating tissue when electrical energy is supplied to the electrodes from the source. The apparatus is positioned at a target tissue site. A tissue type is distinguished utilizing the sensor array to measure a spectral profile of at least one portion of the tissue site. The electrodes are deployed to define an ablation volume that includes at least a portion of the tumor volume. Energy is delivered to the electrodes to ablate or necrose at least a portion of the tumor volume. An amount of tumor volume ablation is determined utilizing the sensor array.

In the embodiment described in claim 57, the method includes delivery of a marking agent to the target tissue site, where at least one of a tumor volume, a tumor surface, an ablated tissue volume, a hyperthermic tissue volume, or an injured tissue volume is marked.

B. The Prior Art

GOUGH ET AL. describe a multiple antenna ablation device. The multiple antenna device includes a primary antenna with a lumen and a longitudinal axis and a distal end sufficiently sharp to pierce tissue, and a secondary antenna at least partially positioned in the secondary antenna. The secondary antenna includes a distal portion configured to be deployed from the lumen in a lateral direction relative to the longitudinal axis, wherein at least a part of a deployed secondary antenna distal portion has at least one radius of curvature. The device is configured to be coupled to an energy source. The device further includes a cooling element coupled to the primary antenna.

BENARON ET AL. relate to a device and method for detecting chemical or histological changes over time in a tissue. The device may include more than one probe to irradiate the tissue and detect the emitted radiation. The device includes an emitter and a detector or an emitter and multiple detectors. The emitter may be an ambient light source, an infrared light source, a laser beam, a light emitting diode, a fluorophore, a radio emitter, a radio wave source, or a self-emitting source.

HOEY ET AL. relate to an apparatus and a method for producing a virtual electrode within or upon a tissue to be treated with radio frequency alternating electric current. The apparatus includes a supply of a conductive or electrolytic fluid to be provided to the patient, an alternative current generator, and a processor for creating, maintaining and controlling the ablation process by the interstitial or surficial delivery of the fluid to a tissue and the delivery of electric power to the tissue via the virtual electrode. The method in accordance with the invention includes the steps of delivering a conductive fluid to a predetermined tissue ablation site for a predetermined time period, applying a

predetermined power level of radio frequency current to the tissue, monitoring at least one of several parameters and adjusting either the applied power and/or the fluid flow in response to the measured parameters.

EDWARDS ET AL. relate to a method of treating a sphincter that provides an apparatus that includes an expandable device coupled to an introducer distal portion and an energy delivery device. The expandable device includes a first arm and a second arm, each with proximal and distal section. The expandable member has a non-deployed configuration and a deployed configuration when the first and second arm distend away from each other. The expandable device is at least partially introduced in the sphincter. At least a portion of the energy delivery device is advanced from the expandable device into an interior of the sphincter. Sufficient energy is delivered from the energy delivery device to create a desired tissue effect in the sphincter. The expandable device is then removed from the sphincter. The introducer may have one or more lumens that may be used as a path for optical fibers.

C. Analysis

1. Legal Standard

According to the MPEP § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations."

2. Rejection over Gough et al. in view of Benaron et al.

Gough et al. and Benaron et al., alone or in combination, fail to teach a method of treating a tumor using an apparatus where at least one of the plurality of resilient members includes an optical sensor operatively connected to function as an emitter and

a detector. Gough et al. makes no mention of an optical sensor functioning as either an emitter or a receptor, much less an optical sensor connected to function as an emitter and a detector. The teaching in Benaron et al. also fails to teach this feature. Benaron et al. teach an apparatus using an emitter and a separate receptor. Further, neither of the references teach a switching device for switching the mode of the optical sensor.

3. Rejection over Gough et al. in view of Benaron et al. and further in view of Hoey et al.

According to M.P.E.P. §2143.03, if an independent claim is non-obvious under 35 U.S.C. then any claim depending therefrom is non-obvious. The rejection of dependent claims 47, 48, and 53 relies on Gough et al. in view of Benaron et al., the deficiencies of which are discussed above. The teaching in Hoey et al. is cited merely for the inclusion of baseline impedance measurements. The teaching in Hoey et al. does not make up for the deficiencies in Gough et al. and Benaron et al., as this reference makes no mention of an optical sensor operatively connected to function as an emitter and a detector or of a switching device.

4. Rejection over Gough et al. in view of Benaron et al. and further in view of Edwards et al.

The deficiencies of Gough et al. and Benaron et al. are discussed above. Edwards et al. is cited merely for a teaching of making a diagnosis based on a measured tissue property. Edwards et al. fail to make any reference to an optical sensor operatively connected to function as an emitter and a detector or of a switching device.

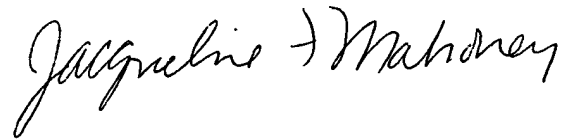
Because the references fail to teach all the claim limitations of the present invention, the standard for obviousness has not been met. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for Allowance. A Notice of Allowance is therefore respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,



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